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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,186	RICHARD ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment dated 1-26-04 is acknowledged.

Claims included in the prosecution are 1-39.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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2. Claims 1-12, 17-18 and 35-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S.

Patent No. 6,183,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant 'fluid in supercritical state' includes supercritical carbon dioxide recited in the claims of said patent. Instant particle sizes are deemed to be included in the generic composition claims in said patent.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that applicant's claims are directed to biocompatible micro particles for inhalation, having a mean diameter of 1-30 micrometers and in contrast the claims of the 783 patent recite microcapsules and method of preparing microcapsules where the microcapsules have a mean diameter between 10 nm and 1 mm or between 20 nm and 50 micrometers. These arguments are not found to be persuasive. First of all, the preamble in a composition claims has no patentable weight especially in view of the **same process** involved in both patented claims and in instant application.

Secondly, as already pointed out instantly claimed diameters fall within the diameters of the patented claims. Contrary to applicant's arguments it is the examiner's position that the obviousness type double patenting made is justified.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8, 11-14, 16-21, 25, 27, 31-32 and 34-39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/313,46 of record.

WO discloses polymeric micro particles for inhalation. The particles are coated with surfactant such as a phospholipid, DPPC, DPPG for example. The particles contain a variety of active principles such as hormones, both protein and non-protein type (insulin, estrogens), antiasthmotics (albuterol). The particles have density of less than 0.4 g/cm³ and a mean diameter of 5-30 microns (note pages 8, 9, 10, 20 and 21, Examples 1, 5-11). The newly added limitation of the weight ratios are met by the reference's teachings on page 38, line 15.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the particles disclosed in the 346 application are structurally different from micro particles of applicant's claims. Applicant further argues that they believe that the particles described in the 346 application are matricial microspheres. These arguments are not found to be persuasive. First of all, arguments based on 'belief' are not the same as arguments based on experimental evidence.

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Secondly, the rejected claims are composition claims and these claims do not reflect the differences between the prior art product and instant product as argued by applicant.

5. Claims 1-8, 10-13, 17-19, 24, 30, 31 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0706821 of record.

EP discloses polymeric micro particles coated with a surfactant (lecithin) prepared by the same method. The particles contain an active principle such as calcitonin. The mean diameter of the particles 20 nm to 100 microns with an apparent density between 0.02 g/cm³ and 0.8 g/cm³ (columns, 2, 3, 5, 6, 7, 11, Examples and claims 1, 5, 6, 11, 17 and 20).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are based on applicant's belief that EP describes particles of metrical structure. This argument is not found to be persuasive since this is not followed by any experimental evidence. It is interesting to note that even in instant particles, the active agent is coated with a coating agent. Doesn't represent a matrical structure?

6. Claims 1-12, 17-18 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2753639 of record.

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FR discloses polymeric coated micro particles prepared by the same method using a super critical fluid and an organic solvent. The particles have a diameter of 20 nm to 500 microns with an apparent density between 0.02 g/cm³ to 0.8 g/cm³. The active agents include peptides (note pages 2, 3, 4, 8, Examples and claims 1, 2, 5, 9-14 and 16). US 6,183,783 (of record) appear to be an English equivalent for FR (abstract, col. 3, line 13 through col. 5, line 8; col. 5, line 35 through col. 6, line 53; Examples and claims of US patent).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the 783 patent discloses subgenuses of the microcapsules and no single microcapsule in the patent is within the size range claimed. This argument is not found to be persuasive since though 783 suggests a broad range of 10 nm and 1 mm, the working examples are in the micrometer range and therefore, the reference qualifies as a 102 reference. Furthermore, applicant himself has not provided examples justifying the broad terms "coating agent" and "medical principle". The rejection is maintained.

7. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/29998.

WO discloses polymeric coated micro particles prepared by the same method using a super critical fluid and an organic solvent (abstract, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant points out to example 1 and argue that in 998, the active principle is dissolved in a solution. This argument is not found to be persuasive since in Example

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pointed out by applicant, the polymer is dissolved in the organic solvent just as in instant method (see instant method claim which recites 'solution of at least one substantially polar coating agent in an organic solvent'. Just as in instant application, which recites, both hydrophilic and lipophilic active agents (insulin is hydrophilic and testosterone is lipophilic), the reference teaches both hydrophilic and lipophilic compounds and therefore, it is implicit that hydrophilic proteins do not dissolve in organic solvents.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 15, 19-20, 22-23, 25-26, 28-29 and 33-39 are rejected under 35 U.S.C.

103(a) as being unpatentable over WO 98/31346 cited above.

WO's teachings have been discussed above. While WO discloses generic 'phosphoglycerides' and phospholipids, it does not teach claimed individual phosphatidylethanolamine and phosphatidylserine. However, in view of WO's exemplification using phosphatidylcholines and its generic teachings, it is deemed obvious to use any phospholipid with the reasonable expectation of success. WO also does not teach the claimed anti-asthmatic agent, beclametasone. However, in view of WO's teachings of other anti-asthmatic agents such as cromolyn, salmetrol, formeterol

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and albuterol, it is deemed obvious to one of ordinary skill in the art to use any known anti-asthmatic agent with a reasonable expectation of success.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again center on the apparent 'matrical microspheres nature of the prior art particles. These arguments have been addressed above.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK